DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 10, 2015

Oxford Performance Materials
Ms. Leigh Ayres
Director, Scientific and Regulatory Affairs
30 South Satellite Road
South Windsor, Connecticut 06074

Re: K142005
Trade/Device Name: SpineFab® Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 3, 2015
Received: June 12, 2015

Dear Ms. Ayres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142005

Device Name
SpineFab® Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*

SpineFab® Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The VBR device is intended for use with autograft and/or allograft bone graft material and must be used with supplemental fixation systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 - SpineFab® VBR 510(k) Summary as Required by Title 21 CFR 807.92(c) for K142005

510(k) Submitter: Oxford Performance Materials, Inc.
P.O. Box 585
30 South Satellite Road
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1-860-698-9300

Contact Person: Leigh Ayres, Director of Scientific and Regulatory Affairs
Date of 510(k) summary statement preparation: July 9, 2015
Proprietary name: SpineFab® Vertebral Body Replacement (VBR) System
Common or Usual Name: Spinal intervertebral body fixation orthosis
Classification: 21 CFR 888.3060
Review Panel: Orthopedic
Medical Device Classification: Class 2
Product Code: MQP
Predicate Devices: the Choice Spine Vertebral Body Replacement (VBR) System (K120570) (primary) and the Pioneer Surgical Technology, Inc. MaxFuse VBR System (K131724).

Description of the Device

The SpineFab® VBR implant is a non-custom implant. The SpineFab® VBR Implants consist of 48 different variations and each one of six different configurations (Small Parallel, Medium Parallel, Large Parallel, Small Lordotic, Medium Lordotic, and Large Lordotic) with the only difference on each configuration being the height. This device is manufactured using polyetherketoneketone (PEKK) polymer using additive manufacturing and contains tantalum radiographic markers.

The implants have an open shaft to allow for the placement of allograft or autograft. The implants have several other features:

- Notches that are an aid to implant insertion,
- Tantalum markers which allow for easy radiographic visualization, and
- Teeth-like structures meant to engage the vertebral endplates for stabilization in vivo.

SpineFab® Vertebral Body Replacement (VBR) System is shipped non-sterile and the sterilization recommendations documented in the instructions for use (IFU) are according to ANSI/AAMI ST79 "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" have been validated.

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Intended Use Statement

SpineFab® Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The VBR device is intended for use with autograft and/or allograft bone graft material and must be used with supplemental fixation systems.

Biocompatibility

Biocompatibility tests were selected according to the FDA guidance document: "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (1995) and the test results obtained from PEKK test specimens were found to be within acceptance criteria described in the ISO 10993-3, 5, 6, 10, 11, and 18 standards.

Performance Testing – Bench Testing

COMPRESSION, TORSION, SUBSIDENCE, AND EXPULSION

This testing was required by UCM072518 "FDA Guidance for Industry and FDA Staff Spinal System 510(k)s" dated 2004. Based on the 2004 guidance, the test specimen design (15x12x50 mm) was the worst case design because it was the "tallest with the smallest cross sectional area." This was confirmed utilizing finite element analysis.

Testing was performed according to:

a. ASTM F2077-11 "Test Methods for Intervertebral Body Fusion Devices,"
b. ASTM F2267-04(2011) "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression," and
c. ASTM draft F-04.25.02.02: Static Expulsion

Comparison of Technological Characteristics with Predicate Devices

The SpineFab® VBR device is substantially equivalent in safety and effectiveness to two other predicate devices cleared by the FDA under 21 CFR 888.3060 spinal intervertebral body fixation orthosis. Those two predicate devices are: the Choice Spine Vertebral Body Replacement (VBR) System (K120570) and the Pioneer Surgical Technology, Inc. MaxFuse VBR System (K131724). Information about the two predicate devices described in this section 5 of this 510(k) submission was obtained from the 510(k) summary documents posted on the FDA 510(k) premarket notification access database.

The intended use statements are substantially equivalent because the scopes of the predicate intended use statements include the intended use statement for the subject device in terms of the location in the spine (T1-L5) and function (vertebral body replacement).

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The two predicates and the subject devices are substantially equivalent in that they are made from Polyaryletherketone (PAEK) polymers. The two predicates are made from polyetheretherketone (PEEK) polymer and the subject device is made from polyetherketoneketone (PEKK) polymer.

The basic design of the two predicates is substantially equivalent regarding sizes, configurations, toothed surfaces, and the acceptance of bone graft material.

The mechanical testing evaluations were substantially equivalent in that the two predicates and the subject device were evaluated according to ASTM standards for static and dynamic axial compression bending, static and dynamic torsion, static subsidence, and static expulsion.

Conclusion

Based on the information provided in the submission, including comparison and bench testing; the SpineFab® VBR device was determined to be substantially equivalent in terms of safety and effectiveness to predicates devices cleared by the FDA.

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